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NEA/IPA FOR ASACHAR EEB/TPP FOR SKEAT USTR FOR FRANCESKI, GROVES, MOWREY PARIS FOR USOECD MHAWLEY-YOUNG

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SUBJECT: IPR/ISRAEL: OCR DOES NOT RESULT IN AGREEMENT

REF: A. TEL AVIV 2173

\*\*B. TEL AVIV 2709

11. SUMMARY: The Special 301 Out-of-Cycle Review (OCR) for Israel, which could have resulted in significant progress on improving Israeli intellectual property (IP) regime in the area of research-based pharmaceuticals, has not yielded an agreement despite strong efforts by the USG to reach one. A proposed exchange of letters formalizing the work of the past eight months was rejected by the GOI as not providing enough incentive to work out a package deal. Rachel Hirschler, Deputy Director of the Foreign Trade Administration, blamed internal factors for Israel's inability to complete negotiations, particularly the current transition period in Israel prior to the upcoming election and a lack of high-level efforts to press key stakeholders to compromise. In addition, Hirschler said that some in the GOI are hoping that by holding out until the next U.S. presidential administration, Israel's name will disappear from the Special 301 Priority Watchlist. The GOI has indicated it would still like to work on IP issues in 2009. END SUMMARY.

## OCR: THE POST MORTEM BEGINS

- $\underline{\P}2$ . Announced last April, the OCR was meant to provide Israel with a special window of opportunity to address the problematic issues of data exclusivity and patent-term extension, the two key IP issues that have resulted in Israel's placement on the Special 301 Priority Watchlist for the past three years. The Office of the United States Trade Representative (USTR) led a delegation to Israel in September and met with key stakeholders from both the research and generic pharmaceutical industries, in addition to holding an interministerial meeting with representatives from the Ministries of Health, Justice, Trade and Finance (Ref A). The meeting was the first time all the relevant ministries were present in one room to discuss IP issues with the USG. While not resulting in an agreement, the visit helped set the terms of the negotiating agenda and seemed to lay the groundwork for further progress.
- 13. By the second interministerial meeting (Ref B) in November, negotiators began closing the gaps on substantive issues, but the GOI's inability to commit made it impossible to complete a deal. The Ministry of Health, responsible for approving pharmaceutical patents and implementing the terms for data exclusivity, did not wish to commit to a package, although it did negotiate on specific terms of data exclusivity -- without reaching final agreement. According to Rachel Hirschler, it appears that TEVA, Israel's largest generic pharmaceutical company, was not in favor of proposals for patent-term extension and was encouraging certain key players to wait until the next U.S. administration, which in

its view might adopt a less firm stance on IP issues.

- Hirschler also stated to econoff that perhaps more problematic for the Israeli side was the lack of high-level government (i.e. ministerial level) support, due to political events and a weak government. The Knesset will likely not meet for at least two months after the general elections (set for February 10) thus making any passing of legislation nearly impossible in the first quarter of 2009. The current situation in Gaza may even result in the elections being postponed, further muddying the prospects for a quick resolution of the IP situation. Our key contact at the Ministry of Health, Yoel Lipshitz, was recently summoned to the Gaza Strip as part of his reserve duty, effectively ending his availability to negotiate on IP. In a brief respite from military duty, he met with Econoffs, and emphasized that waiting for the next administration in both the United States and in Israel was not for reasons of ascertaining a better deal, but rather would ensure that an agreement would have the high-level buy-in necessary for legislation in 2009.
- 15. USTR sought to formalize IP commitments from Israel in an exchange of letters. Hirschler said that Israel could not commit to putting anything in writing. She added that in exchange for promises to address data exclusivity and patent-term extension, Israel would require firm USG commitments regarding the Special 301 process.

## NEXT STEPS?

 $\underline{\ }$ 6. The GOI has emphasized that it still wishes to work with USTR and even proposed a meeting in February on the IP issue.

However, by that time, the regular Special 301 review process will have begun and Israel will likely still not have the high-level leadership in place to move forward. According to Lipshitz, the GOI still very much hopes to meet with USTR in 2009 on this issue.

## COMMENT

17. While the inability of Israel to complete the OCR is disappointing, gains were made during the process that hopefully can be capitalized on in the future. USTR was closing the gaps on substantive issues, and at times the discussion seemed to bring the parties very close to an agreement. It is unfortunate that certain unpredictable factors such as timing did not work in favor of an agreement at this time, as it is very difficult to predict the position of a future Israeli government on IP issues. That being said, Post encourages the relevant USG agencies to meet with the GOI and to keep the pressure on Israel to improve its IP regime, both informally and through formal channels like the Special 301 process and Israel's accession to the Organization of Economic Cooperation and Development (OECD).

\* Visit Embassy Tel Aviv's Classified Website: http://www.state.sgov.gov/p/nea/telaviv \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* CUNNINGHAM